(1) Name, address, and phone number of the reporter who initially provided information to the user facility, manufacturer, or distributor;

(2) Whether the initial reporter is a health professional;

(3) Occupation; and

(4) Whether the initial reporter also sent a copy of the report to FDA, if known.

(e) Importer information (Block F) shall contain the following:

(1) Whether reporter is an importer;

(2) Importer report number;

(3) Importer address;

(4) Contact person;

(5) Contact person's telephone number;

(6) Date the importer became aware of the event (month, day, year);

(7) Type of report (initial or followup (if followup, include report number of initial report));

(8) Date of the importer report (month, day, year);

(9) Approximate age of device;

(10) Event problem codes—patient code and device code (refer to FDA ''Coding Manual For Form 3500A'');

(11) Whether a report was sent to FDA and the date it was sent (month, day, year);

(12) Location, where event occurred;

(13) Whether a report was sent to the manufacturer and the date it was sent (month, day, year); and

(14) Manufacturer name and address; if available.

## Subpart E—Manufacturer Reporting Requirements

### § 803.50 Individual adverse event reports; manufacturers.

(a) *Reporting standards.* Device manufacturers are required to report within 30 days whenever the manufacturer receives or otherwise becomes aware of information, from any source, that reasonably suggests that a device marketed by the manufacturer:

(1) May have caused or contributed to a death or serious injury; or

(2) Has malfunctioned and such device or similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur.

(b) *Information that is reasonably known to manufacturers.* (1) Manufacturers must provide all information required in this subpart E that is reasonably known to them. FDA considers the following information to be reasonably known to the manufacturer:

(i) Any information that can be obtained by contacting a user facility, importer, or other initial reporter;

(ii) Any information in a manufacturer's possession; or

(iii) Any information that can be obtained by analysis, testing or other evaluation of the device.

(2) Manufacturers are responsible for obtaining and providing FDA with information that is incomplete or missing from reports submitted by user facilities, importers, and other initial reporters. Manufacturers are also responsible for conducting an investigation of each event and evaluating the cause of the event. If a manufacturer cannot provide complete information on an MDR report, it must provide a statement explaining why such information was incomplete and the steps taken to obtain the information. Any required information not available at the time of the report, which is obtained after the initial filing, must be provided by the manufacturer in a supplemental report under § 803.56.

[60 FR 63597, Dec. 11, 1995, as amended at 66 FR 23157, May 8, 2001]

### § 803.52 Individual adverse event report data elements.

Individual medical device manufacturer reports shall contain the following information, known or reasonably known to them as described in § 803.50(b), which corresponds to the format of FDA Form 3500A:

(a) Patient information (Block A) shall contain the following:

(1) Patient name or other identifier;

(2) Patient age at the time of event, or date of birth;

(3) Patient gender; and

(4) Patient weight.

(b) Adverse event or product problem (Block B) shall contain the following:

(1) Adverse event or product problem;

(2) Outcomes attributed to the adverse event, e.g., death; or serious injury, that is:

(i) Life threatening injury or illness;